UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CAROL LEWIS, Plaintiff, v. THOMAS E. PRICE Secretary, United States Department of Health and Human Services, Defendant.	)	Civil Action No.: 1:15-CV-13530-NMG

HHS'S REPLY TO PLAINTIFF'S OPPOSITION TO HHS' MOTION TO AFFIRM HHS' DECISION AND REPLY TO DEFENDANT'S OPPOSITION TO HHS' MOTION FOR SUMMARY JUDGMENT

For the reasons set forth below, Defendant, the Secretary of the Department of Health and Human Services ("HHS" or "Defendant"), requests that the Court dismiss the Complaint and/or affirm HHS' decision that Plaintiff is not entitled to the requested relief regarding Medicare coverage for the Continuous Glucose Monitoring (CGM) device that she used at the time that she filed her Complaint.

I. THE COMPLAINT SHOULD BE DISMISSED UNDER RULE 12(b)(1).

The court lacks subject matter jurisdiction over a claim when the plaintiff lacks a legally cognizable interest in the outcome." *Cruz v. Farquharson*, 252 F.3d 530, 533 (1st Cir. 2001). A claim is moot when a court cannot provide effectual relief because no justiciable case remains. *Oakville Dev. Corp. v. FDIC*, 986 F.2d 611, 613 (1st Cir. 1993); *Murphy v. Hunt*, 455 U.S. 478, 481 (1982). Dismissal of the action under Rule 12(b)(1), Federal Rules of Civil Procedure, is compulsory when the action is moot. *ACLU of Mass. v. U.S. Conf. of Catholic Bishops*, 705 F.3d 44, 57 (1st Cir.2013) (citing *Camreta v. Greene*, 131 S.Ct. 2020, 2034-2035 (2011)).

Cruz, 252 F.3d at 533. *See Mangual v. Rotger-Sabat*, 317 F.3d 45, 60 (1st Cir. 2003) ("If events have transpired to render a court opinion merely advisory, Article III considerations require dismissal of the case."); *see also Kingdomware Technologies, Inc. v. United States*, 136 S. Ct. 1969 (2016) ("no live controversy in the ordinary sense remains because no court is now capable of granting the relief petitioner seeks"); *Spencer v. Kemna*¸ 523 U.S. 1, 18 (1998).

At the time that Plaintiff challenged HHS' denial of coverage for the CGM that she was using, Plaintiff was using a Medtronic CGM. Memorandum of Law in Support of HHS' Motion to Affirm HHS' Decision and in Opposition to Plaintiff's Motion for Summary Judgment ("HHS' Mem.") at 8. The Medtronic CGM measured Plaintiff's interstitial glucose levels (the glucose levels in the fluid surrounding the cells of the tissue beneath the skin) to assist in determining whether she should proceed to test her blood glucose levels using a home blood glucose monitor (the home blood glucose monitor measures the blood glucose level directly, through use of a sterile lancet that draws a drop of blood; the blood is placed on a reagent strip and inserted into the glucose monitor to obtain a blood glucose reading.). HHS Mem. at 6-7. The issue raised by the Complaint was whether HHS improperly determined that Plaintiff's CGM was not Durable Medical Equipment ("DME") and therefore not covered by Medicare. HHS Mem. at 3-4. HHS determined that the CGM was not DME because it was merely "precautionary" equipment, not serving a medically necessary purpose because it was not reliable enough for making therapeutic decisions, i.e., deciding whether or not to increase or decrease insulin. HHS Mem. at 7. That is, HHS determined that medically reliable results were obtained from the home blood glucose monitor, not from any reading from Plaintiff's CGM. *Id.*

However, Plaintiff is no longer using the Medtronic CGM. As she points out in her Opposition to HHS' Motion to Affirm HHS' Decision and Reply to Defendant's Opposition to

Plaintiff's Motion for Summary Judgment ("Plaintiff's Reply Mem.), at 10 n. 12, Plaintiff now uses a "Dexcom G5" CGM. Unlike the Medtronic CGM placed at issue in the Complaint, the Dexcom G5 is approved by the U.S. Food and Drug Administration as a device "designed to replace fingerstick blood glucose testing for diabetes treatment decisions" and test results from the device can be used to make diabetes treatment decisions. *See Dexcom G5 Mobile Continuous Glucose Monitoring System – P120005/S041*, U.S. Food and Drug Administration, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm533969.htm (Dec. 21, 2016). HHS Mem. at 17. Because the FDA has determined that the Dexcom G5 CGM provides reliable test results for blood glucose levels and can, therefore, be used for determining diabetes treatment, HHS has qualified the Dexcom G5 as a medically necessary device, it qualifies as DME, and it is eligible for reimbursement by Medicare. [1]

Accordingly, Plaintiff's general requests for court orders relating to coverage of CGM's – is moot, since ". . . an intervening circumstance deprives the plaintiff of a "personal stake in the outcome of the lawsuit." *Genesis Healthcare Corp. v. Symczyk*, 133 S.Ct. 1523 (2013) (quoting *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477-478 (1990)); *ACLU of Mass*, 705 F.3d at 57.

[1] As explained in HHS' mem., HHS decision to extend Medicare coverage to therapeutic CGM's, CMS Ruling No. 1682, was issued on January 12, 2017, and provides that therapeutic CGM's, -- . CGM's that have been approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions -- fall within the Medicare Part B benefit category for DME if the reasonable and necessary criteria under 42 U.S.C. § 1395y(a)(1)(A)) are met. Plaintiff's Dexcom G5 is the only CGM approved for this purpose, the only CGM falling within the parameters specified by CMS Ruling No. 1682 as DME, and, as noted, the only CGM covered by Medicare.

II. PLAINTIFF MISCHARACTERIZES NCD 280.1 AND IMPROPERLY ANALOGIZES CGMs TO DME DEVICES THAT HHS HAS APPROVED.

Should the Court decline to dismiss the Complaint under Rule 12(b)(1), Plaintiff has failed to show that HHS' denial of Medicare coverage for Plaintiff's CGM is invalid under 42 U.S.C. § 405(g). *See* Report and Recommendation of the Magistrate at 24 (adopted by the Court). *See* HHS' Mem. 13-19 and *in passim.* In her Reply, Plaintiff sets forth her position that her CGM must be considered a DME because, in her view, HHS has deemed other "adjunctive" or precautionary devices as DME and Medicare reimbursable. Plaintiff's Reply Mem. at 4-6. Plaintiff refers to National Coverage Determinations ("NCDs") that, Plaintiff avers, use the terms "augmentative" and "adjunctive" to other medical products reimbursable under Medicare.

Plaintiff's reliance on the items listed in the NCDs is misguided because those items have undergone an arduous scientific and public clearance process that most CGMs , including Plaintiff's Medtronic CGM, have not. The process of making a National Coverage Determination requires HHS to provide the public with notice of the proposed determination, conduct meetings with advisory committees with respect to the determination, consider applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination, provide a clear statement for the basis of the determination, and make available to the public the data considered in the determination. 42 U.S.C. § 1395y(a), (l). As a result, each device and other item that Plaintiff's argument refers to has undergone an extensive medical approval process. Since the Medtronic CGM – and other CGM's -- have not been approved through this process, comparing a CGM to DME covered by an NCD is inappropriate since, as noted, the comparison fails to take into account the significant medical and public proceedings involved in making the coverage determinations in the NCD.

In addition, Plaintiff mischaracterizes the language of the NCD's. For instance, Plaintiff fails to point out that NCD 280.1 provides that "[i]n the case of equipment categories that have been determined by CMS to be covered under the DME benefit, the list outlines the conditions of coverage that must be met if payment is to be allowed for the rental or purchase of DME by a particular patient, or cross-refers to another section of the manual where the applicable coverage criteria are described in more detail." (emphasis added). "Conditions of coverage" is important regarding Plaintiff's example of continuous passive motion devices. Plaintiff's Rely Mem. at 4. Plaintiff asserts that these devices are "DME used as an adjunct to physical therapy following surgery[,]" But, to the contrary, NCD 280.1 does not classify the devices as adjunctive, and it places very strict conditions of Medicare coverage upon them. NCD 280.1 specifies that coverage of continuous passive motion devices is only permitted if use is commenced within two days following a knee replacement and coverage is limited to the three week period following the surgery; NCD 280.1 specifically notes "[t]here is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications."

Finally, Plaintiff's characterizations of NCD 280.1, Plaintiff's Reply Mem. at 4-6, are contradicted by NCD 280.1, which does not use the terms "adjunct," "adjunctive," or "precautionary" in its approval of DME devices and other items. To the contrary, the NCD uses the word "precautionary" to explain why certain items are not covered as DME. *See* NCD 280.1, Portable Oxygen Systems, Preset, Preset Portable Oxygen Units, and Spare Tanks of Oxygen. Accordingly, Plaintiff's analogies to the items listed as DME in NCDs are useless in supporting her arguments.

III. THE COURT MAY NOT CONSIDER NEW EVIDENCE SUBMITTED BY PLAINTIFF THAT IS NOT IN THE ADMINISTRATIVE RECORD.

A plaintiff may not present new evidence to this Court that is not in the administrative record to argue that HHS lacked substantial evidence to support its decision. 42 U.S.C. § 405(g); 42 U.S.C. § 1395ff; *Mathews v. Weber*, 423 U.S. 261, 263) (1976) ("under 42 U.S.C. § 405(g), the 'court may consider only the pleadings and administrative record' and 'neither party may put any additional evidence before the district court[,];"*Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 102 (D. Mass. 2009) *and cites therein.* ("The court's factual review is limited to the administrative record")

Plaintiff Reply Mem. sets forth information to support her argument that is not in the administrative record. Plaintiff: (1) points to an article titled, "Power to the People! How the Voice of People with T1D Can Influence Regulatory Decisions" to support the proposition, which she is making for the first time, that "[l]ess than 12% of CGM users report always confirming a reading with a finger stick[,]", and (2) refers to an article titled "Persistence Triumphs: Getting Medicare to Cover My CGM[,]" to support the proposition – that she sets forth for the first time --, that the Secretary of HHS has issued more than 40 final decisions finding that CGM primarily serves a medical purpose. Pl. Opp. to HHS' Motion to Affirm HHS' Decision at 4, 8.

Moreover, the article entitled "Persistence Triumphs: Getting Medicare to Cover My CGM[,]" does not refer at all to Plaintiff's new allegation that HHS has issued more than 40 final decisions that her CGM primarily serves a medical purpose.

IV. PLAINTIFF'S ARGUMENTS REGARDING ALJ DECISION NO. CR4596 ARE MISBEGOTTEN BECAUSE THE DECISION WAS OVERTURNED UPON ADMINISTRATIVE APPEAL.

In the Complaint and throughout Plaintiff's Motion for Summary Judgment, Plaintiff repeatedly attempts to rely on ALJ Decision No. CR4596 and its proceedings. This decision came in a separate administrative challenge that Plaintiff brought regarding an HHS' general policy determination, Local Coverage Determination ("LCA") L11530/L33822 and Local Coverage Article A33614/A52464, policies generally denying Medicare reimbursement for CGM's. The ALJ Decision ruled in Plaintiff's favor to the effect that CGM's were not precautionary but serving a medical purpose and entitled to reimbursement as DME's. Complaint ¶¶ 97-98; Pl. Motion for Summary Judgment at 9-10.[2] Plaintiff included a challenge to the LCA in her Complaint, but this Court dismissed Plaintiff's challenge as unripe for review, distinguishing it from Plaintiff's claim for individual relief, although Plaintiff has continued to rely on the ALJ's decision. *Id.* Whatever the merits of relying on the ALJ Decision CR4596 at earlier stages of this proceeding, Plaintiff cannot rely on the ALJ Decision in any respect because the ALJ's decision has been overturned on administrative appeal. On April 10, 2017, the Appellate Division of the HHS Departmental Appeals Board issued its decision reversing the ALJ's decision, vacating "[the ALJ's] conclusion that the challenged policy is invalid under the reasonableness standard," and dismissing the administrative complaint. *LCD Complaint: Glucose Monitors (L11530/L33822 and Local Coverage Articles A33614/A52464),* Decision No. 2782. Accordingly, no weight can be accorded Plaintiff's repeated arguments that her CGM's are entitled to Medicare reimbursement based on ALJ Decision No. CR4596.

[2] Plaintiff filed a Motion for Leave to File Supplemental Authority on May 4, 2016, in order to file ALJ Decision No. CR4596 with the Court. E-File Doc. 32. The Motion was granted and on May 19, 2016, in E-File Document 35-1, Plaintiff filed the Decision, making it a part of the record in this case.

V. CONCLUSION

For these reasons, and the reasons set forth in HHS' Memorandum in Support of Motion to Affirm HHS' Decision. . . , Defendant requests that the Court dismiss the Complaint under Rule 12(b)(1) because Plaintiff lacks standing as to mootness, or, in the alternative, hold that HHS is entitled to summary judgment because Plaintiff cannot demonstrate that HHS' denial of Medicare coverage for Plaintiff's CGM's lacks support by substantial evidence in the administrative record.

Respectfully submitted,

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Certificate of Service

I certify that the foregoing will be filed through the electronic filing system of the Court, which system will serve counsel for Plaintiff electronically, on this twelfth day of April 2017.

/s/ Anita Johnson